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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,242

01/26/2004

Yukiko Sasaki

46240

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20736 7590 12/18/2006
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EXAMINER

ZHENG, LI

ART UNIT

PAPER NUMBER

1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/18/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/763,242

Applicant(s)

SASAKI ET AL.

Examiner

Li Zheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/700,187.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1262004/7262005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse Group I, claims 1-8, 11 and 14 and SEQ ID NO: 1, cancellations of claims 9-10 and 12-13 and the amendment to claim 16 are acknowledged in the reply filed on 9/25/2006. Applicants argue that SEQ ID NO: 3 encompasses SEQ ID NO: 1 and prior art searches for SEQ ID NO: 1 and 3 are coextensive. Applicant's argument is found persuasive and restriction requirement between SEQ ID NO: 1 and 3 is withdrawn. Applicants are advised that since the restriction between SEQ ID NO: 1 and 3 is withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

The examiner, however, maintains all other restriction requirements.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy and its certified translation have been filed in parent Application No. 09/700,187, filed on 11/13/2000 and 11/12/2002, respectively.

Specification

3. The disclosure is objected to because of the following informalities:

The status of the U.S. application recited in the specification amendment filed on 1/26/2004 needs to be updated.

Appropriate correction is required.

4. The specification is objected to under 37 CFR 1.821(d) as failing to refer to a sequence by use of its sequence identifier preceded by "SEQ ID NO:". The nucleotide sequences and the protein sequence in Figures 1 and 6-7 should be identified with SEQ ID NOs:, respectively. Alternatively, the brief descriptions of those figures on pages 6-9 can be amended to recite the identifiers.

Claim Objections

5. Given that "a sequence obtained by deletion of one or more nucleotides from the nucleotide sequence of SEQ ID NO: 2 provided that the core sequence of SEQ ID NO:

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1 is maintained" encompasses any sequence containing the SEQ ID NO: 1 regardless its homology to SEQ ID NO: 2, claims 1-3, claims 4-5, and claims 11 and 14 cover essentially same scopes of invention, respectively. Applicant is advised that should claim 1, 4 and 11 be found allowable, claims 2-3, 5 and 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4, 5, 7, 8, 11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "both said DNA fragment and expression of a promoter", renders the claim indefinite. It is unclear what is the other element of "both".

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The metes and bounds are unclear. It is suggested to remove "expression of " from the recitation.

Further, the recitation on line 3, "of a peptide-coding sequence", render the claim indefinite. It is unclear the recitation is to limit "a plant" on line 3 or "expression" on line 2. The metes and bounds are not clear. It is suggested to place the recitation "in a plant cell or a plant" preceding to the recitation "are repressed by irradiation" on line 5. The same rejection is also applied to claim 4.

7. Claims 1-8, 11 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide sequence of SEQ ID NO: 2 and 9 copies of SEQ ID NO: 1 as light responsive elements in pea, as well as SEQ ID NO: 3 together with several variants made by deletions (as illustrated in PL1-PL4 of figure 4) as light responsive promoters in pea does not reasonably provide enablement for those sequences above being light responsive elements or promoters in any plant, or all the sequences containing SEQ ID NO: 1 as light responsive sequences or promoters in pea, or SEQ ID NO: 2 alone as light responsive promoter in pea. The specification does not enable any person skilled in the art to which it pertains with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches that a promoter a 2129 promoter region of pra2 gene encoding a small G protein was cloned and sequenced (Figure 1). Through various deletion of upstream region of the promoter, the 93 bp sequence of SEQ ID NO: 2 was identified as a cis-element involved in light-repressible expression (page 19-23, examples 3 and 4; also Figures 3). The specification further demonstrates that 93 bp cis-element combined with other promoters such as 35S90 could drive light-repressible gene expression (Figure 4; also pages 23-24, example 5). Further deletion analysis of SEQ ID NO: 2 identified a 31-bp region as a phytochrome-responsive cis-element (pages 24-25, example 6; also Figure 5). The specification further shows that analysis using a linker scanning assay and a gel shift assay identified the 12-bp core sequence of SEQ ID NO: 1 which is essential for light-repressible expression (Figures 6 and 7; also pages 25-28, Examples 7 and 8). The specification finally demonstrates that 9 copies of SEQ ID NO: 1 combined with minimal promoter of CaMV 35S could drive light repressible expression in pea (pages 28-31, Example 9; also Figure 8)

However, there is no evidence that SEQ ID NO: 2 alone could drive light repressible expression without combining with other promoters or other parts of SEQ ID NO: 3. Therefore, SEQ ID NO: 2 could only is a light responsive element and serves as a part of light repressible promoters. The only enabled light repressible promoters comprising SEQ ID NO: 1 are SEQ ID NO: 3 together with several variants made by deletions (as illustrated in PL1-PL4 of figure 4). Without further guidance, undue experimentation would be required to use SEQ ID NO: 2 alone as a promoter.

Further, although SEQ ID NO: 1 is shown to be essential for SEQ ID NO: 3 or 2 and a tandem repeat containing 9 copies of SEQ ID NO: 1 is sufficient to serve as a light responsive element and form a light repressible promoter in combination with other minimum promoters, there is however no evidence to suggest that SEQ ID NO: 1 alone (one copy) or any sequence containing SEQ ID NO: 1 would be functional as SEQ ID NO: 2, 3, or the sequence containing nine copies of SEQ ID NO: 1. The light repressible expression is merely a final outcome of function of the promoter. The mechanism is still unknown. For example, the nature of the transacting factor(s) that might bind to SEQ ID NO: 1 is unknown. It is also not known the interactions between said transacting factors and the RNA polymerase that produces mRNA as evidenced by the loss of the light responsiveness of GF1 construct in Figure 4. Given that "a sequence obtained by deletion of one or more nucleotides from the nucleotide sequence of SEQ ID NO: 2 provided that the core sequence of SEQ ID NO: 1 is maintained" encompasses any sequence containing the SEQ ID NO: 1 regardless its homology to SEQ ID NO: 2. The specification neither provide evidence to enable any sequence containing SEQ ID NO: 1 nor provides the guidance as to how to modify SEQ ID NO: 2 in addition to maintaining the core sequence of SEQ ID NO: 1. undue experimentation would be required to any sequences containing SEQ ID NO: 1 as light responsive elements.

Still further even if SEQ ID NO: 1-3 are enabled in pea, there is no evidence suggesting that those elements would likely work similarly in other plants. The binding of transcriptional factor with its cognate cis-element is highly specific. There is no evidence showing either that most of the plants employ similar transcriptional factors which bind

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to SEQ ID NO: 1 to confer light responsiveness or that SEQ ID NO: 1 exists in the promoters of many light-repressible genes in various plants. On the contrary, Ngai et al. (1997, The Plant Journal 12:1021-1034) teach a 124 bp cis-element in the promoter region of a light-repressible gene AS1 from pea (page 1027, the paragraph bridging the left and the right column). SEQ ID NO: 1 is, however, not found in the cis element of Ngai et al. This reference suggests that a pea plant employs various transcription factors and cis-elements to regulate genes repressed by light. Without further guidance, undue experimentation would be required for a person skilled in the art to use claimed elements as light responsive elements in other plants. See *Genentech Inc. v. Novo Nordisk, A/S* (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen et al. (Genbank Accession: K03266, 1985) or Okubo et al. (Genbank Accession D25785, 1995) or Richards et al. (Genbank Accession: Z12170, 1992).

Jansen et al. teach a 145 bp genomic sequence comprising SEQ ID NO: 1 from chicken. Okubo et al. teach a 147 bp cDNA sequence comprising SEQ ID NO: 1 from human. Richards et al. teach a 1790 bp genomic region comprising SEQ ID NO: 1 from Arabidopsis. The property as being able to form a light-repressible promoter in a plant when linked to a promoter is inherent to the sequences of Jason et al., Okubo et al. and Richards et al. Given that "a sequence obtained by deletion of one or more nucleotides from the nucleotide sequence of SEQ ID NO: 2 provided that the core sequence of SEQ ID NO: 1 is maintained" encompasses any sequence containing the SEQ ID NO: 1 regardless its homology to SEQ ID NO: 2, The reference thus meet all the limitations set forth by instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 and 8 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Richards et al. (Genbank Accession: Z12170, 1992)..

Claims 4-6 and 8 require a sequence comprising SEQ ID NO: 1 which is a promoter. Richards et al. teach a 1790 bp genomic region comprising SEQ ID NO: 1 from Arabidopsis as claimed in the instant application but does not mention that such a

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genomic region is a promoter as claimed. The examiner is unable to determine whether the prior art disclosure possesses the unrecited characteristics or property. See *In re Best* 195 USPQ 430, 433 (CCPA 1977). The examiner is not in a position to make a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if and how the claimed subject matter differ from the prior art. Accordingly, the burden shifts to the Applicant to provide evidence that the prior art neither anticipates nor renders obvious the claimed invention.

Conclusion

Claims 1-8, 11 and 14 are rejected.

No claim is allowed.

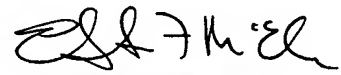
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ELIZABETH MCELWAIN
PRIMARY EXAMINER

